REMARKS

Rejections under 35 U.S.C. §103

Claims 27, 29, 31, 33, 34, 37, 40, 42 are allegedly rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,464,610 to Hayes, et al. (hereinafter "Hayes"), in view of U.S. Patent 5,648,389 to Gans et al.(hereinafter "Gans"), and a publication found in Merck Veterinary Manual of 1965 as further combined with U.S. Patent 6,071,541 to Murad, (hereinafter "Murad-I") and published U.S. application 2003/0007939, also to Murad (hereinafter "Murad-II").

The present application is a divisional of application serial no. 09/545,486, now allowed, which claims priority from the provisional having serial number 60/128,605, filed April 8, 1999. The present claims are directed to methods for the treatment of onychomychosis through the topical application of the recited composition.

Applicant disagrees with the proposed relevance of the Merck Veterinary Manual as it discloses treatment methods of foot rot through soaking the foot in a copper sulfate solution. The present claims are directed to a method for the treatment of onychomychosis, not the treatment of foot rot. The present claims are not to a composition, rather are directed to a method for the treatment of onychomychosis, a fungal infection afflicting the nail. Applicant respectfully submits the Merck reference to be directed to methods of treatment of a non-claimed ailment. Therefore, this reference is not prior art against the pending claims.

Hayes is directed to a method for treating onychomychosis comprising administering a medical device containing salicylic acid to the afflicted nail. Optionally, other ingredients can be included in the composition "to assist penetration of salicylic acid into the nail." Column 4 lines 38-40. Hayes **only** suggests the inclusion of additional components which would enhance trans-nail permeation of the salicylic acid. Hayes does not suggests inclusion of other components. Moreover, Hayes does not even suggests the desire to include other items in the treatment composition. Nor, does Hayes motivate one of ordinary skill to include non-permeation enhancing components. Hayes does not disclose each and every element of the

present claims. Hayes does not even imply the desire for other components in their treatment composition. Indeed, Hayes presents the treatment composition as complete as disclosed, it is only through attempting to re-create Applicant composition that any combination of art is attempted. Furthermore, Applicant respectfully submits it is an unsupportable leap to combine non-analogous art, especially without express or implied motivation. There is nothing in Hayes to motivate examination of an acne treatment method, which is Gans. One of skill in the art would not be motivated to examine, much less combine art regarding the treatment of acne and related skin issues in the treatment of a fungal infection of the nails.

Gans is directed to

> "compositions for the treatment of dermatological disorders and, in particular, to topical compositions for the treatment of dermatological conditions arising from changes in normal keratinization, epidermal formation or pilosebaceous function, such as acne, psoriasis, seborrhea, ingrown hairs and pseudofolliculitis barbae, and hyperpigmented skin." Column 1 lines 6-12.

Acne and psoriasis are ailments exclusive to the dermis thereby excluding the nail. Disclosure regarding treatment of onychomychosis is absent. Gans is NOT directed to the treatment of onychomychosis. One of skill in the art would not be motivated to examine, much less combine art regarding the treatment of acne with a treatment of nails. Even if the Office were to assert motivation to combine, the combination of Gans with Hayes results in inoperable embodiments. The combination of the surfactants of Gans into the plaster of Hayes would result in an inoperable embodiment because the surfactants would prevent the curing of the plaster.

The Office Action also asserts that Murad-II at [0062] discloses Zn and EDTA. However, the cited paragraph merely discloses example organic and inorganic **bases**, from which acid salts can be made. Murad-II does not disclose a transition metal coordination complex. There is no language disclosing the combination of the Zn and the EDTA. The mere mention of Zn and EDTA does not disclose a coordination complex formed therebetween.

The present disclosure teaches the use of a copper composition in the treatment of onychomychosis. Applicant further submits that there is no disclosure or teaching in any of the cited references, regarding the use of a copper composition for the treatment of onychomychosis. Therefore, the inclusion of a copper composition in the presently claimed method cannot be simply so as to optimize the desired effects, because the effects thereof were not described in the art. Indeed, contrary to the Office's assertion on page 3 of the Office Action, no desired effects correlating to the use of a copper composition were described and therefore none could be optimized. Since results from the use of a copper composition were not disclosed, it is an unsupportable leap of logic to propose the inclusion of a copper composition so as to optimize an undisclosed attribute. Therefore, the selection of a copper composition is not a result effected parameter chosen to obtain the desired effects, as proposed by the Office.

Additionally, column 1 lines 10 through 36 of Hayes teaches away from the use of a topical treatment for onychomychosis. A teaching away is *prima facia* evidence of non-obviousness. Such a teaching away would deter general and implied motivation to combine, even if such motivation were found, which Applicant maintains is absent. Moreover, this teaching away would deter combining Hayes with simple topical treatment compositions, such as disclosed in Murad-I, Murad-II or Gans. Applicant respectfully submits, therefore, that the Office has failed to establish a *prima facie* case under 35 U.S.C. §103 of claims 27, 29, 31, 33, 34, 37, 40 and 42.

Further, neither Gans, nor Murad-I, nor Murad-II enable treatment of onychomychosis. These disclosures are directed to the treatment of skin. The mere mention of the nail ailment does not provide one of skill in the art with sufficient information whereby the present method is obvious in view thereof. Indeed, these disclosures are directed to causing skin hydration and skin exfoliation. These and similar dermatological actions do not occur on a nail. Moreover, there are no analogous reactions or results to which these disclosures relate. Therefore, these disclosures are directed to non-analogous art and cannot support the Office's rejections.

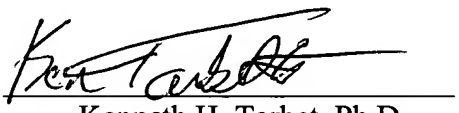
Rejections under 35 U.S.C. §112

Regarding the rejection of claim 45 under 35 U.S.C. §112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 45 has been amended herewith to more fully point out and distinctly claim the invention. Specifically, the phrase "the hydrophilic carrier" was replaced by the phrase "the pharmaceutically acceptable carrier." In light of this amendment, Applicant respectfully submits this rejection to be overcome.

Applicant request reconsideration in light of these arguments and amendments. Applicant respectfully submits that the claims are in condition for allowance. Early notification of such is earnestly solicited.

Respectfully submitted,

Dated: September 27, 2004

By: 

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